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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,406	10/07/2002	Ralf-Christian Scholthauer	DAIRY 71.001APC	6927

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EXAMINER	
PRATS, FRANCISCO CHANDLER	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,406	SCHOLTHAUER ET AL.	
	Examiner	Art Unit	
	Francisco C. Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 28, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,22-30 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,22-30 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

LLC

DETAILED ACTION

The amendment filed January 28, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1-19, 22-30 and 32-36 are pending and are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7, 13-18, 22, 23, 27-29 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ju et al (J. Dairy Sci. 78:2119-2128 (1995)).

Ju discloses the hydrolysis of whey protein isolate (WPI) with three different neutral proteases, porcine trypsin,

Neutrase ®, and BLP (*Bacillus licheniformis* protease), at pH 7.0 (with a shift to 6.5-6.7 during hydrolysis) and 40° C, the reaction being stopped by dilution and pH change to 2.5 degree. See page 2120, left column, paragraph entitled "Hydrolysis of WP." The final degree of hydrolysis was 8.4 ± 1.2% for Neutrase ®, 6.7 ± .81% for trypsin, and 4.9 ± .19% for BLP. Thus, because Ju contacts the claimed substrate with the claimed enzyme under the claimed conditions, a holding of anticipation of the cited claims over Ju is required.

Note specifically that Ju is considered to anticipate those claims reciting specific peptides because the same starting material as recited in the claims was combined with the same enzyme as recited in the claims, and subjected to the same hydrolytic conditions. Therefore the same result must inherently have occurred, and that inherent result includes the production of a hydrolysate comprising the specific peptides recited in applicant's claims.

Claims 1, 3, 5, 6, 13-19, 22, 23, 27-30 and 32-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Davis et al (U.S. Pat. 6,630,320 B1).

Davis discloses the hydrolysis of whey protein isolate (WPI) with the neutral proteases, porcine trypsin, at pH 8.0 and

40° C, the reaction being stopped by heat treatment at 75 to 85° C for 15 seconds, to produce a hydrolysate termed "601" therein. See column 5, line 41 through column 7, line 15. The final degree of hydrolysis of the 601 product was 4.5 to 6.5%. The 601 product is disclosed as being suitable for treating hypertension. See, e.g., column 9, lines 48-55. Thus, because Davis contacts the claimed substrate with the claimed enzyme under the claimed conditions, and uses that product to treat hypertension, a holding of anticipation of the cited claims over Davis is required.

Note specifically that Davis is considered to anticipate those claims reciting specific peptides because the same starting material as recited in the claims was combined with the same enzyme as recited in the claims, and subjected to the same hydrolytic conditions. Therefore the same result must inherently have occurred, and that inherent result includes the production of a hydrolysate comprising the specific peptides recited in applicant's claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19, 22-30 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlothauer et al (WO 99/65326) in view of Ju et al (J. Dairy Sci. 78:2119-2128 (1995)).

Schlothauer describes the production of polypeptides from whey using neutral proteases including Neutrase (see, e.g., claims 6-8 on page 20), acid proteases (see Example 14 on pages 13 and 14), and alkaline proteases (see page 5, lines 15-16). Schlothauer describes the claimed variety of deactivation methods recited in claims 5-10 (see, e.g., pages 5-6), as well as the claimed immobilization techniques (page 5, lines 5-8). Schlothauer further discloses the preparation and use of the

peptide MKG as recited in claims 15, 18, 21, 27 and 33 (see, e.g., page 4, lines 33-36).

Schlothauer differs from the claims under examination in that Schlothauer does not disclose the use of WPI as the starting material in the hydrolysis processes. However, Schlothauer generically discloses that the desired bioactive peptides can be made from a "whey protein containing substrate" (page 4, first line). Thus, the artisan of ordinary skill, recognizing from Ju that WPI is a whey protein containing substrate which can be hydrolyzed by the enzymes disclosed in Schlothauer, clearly would have been motivated to have used Ju's WPI in Schlothauer's process which uses a whey containing substrate. Thus, because WPI specifically fits the category of starting material required by Schlothauer, the artisan of ordinary skill would have been motivated to have used it in Schlothauer's process.

Claims 1-19, 22-30 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlothauer et al (WO 99/65326) in view of Davis et al (U.S. Pat. 6,630,320 B1).

As discussed above, Schlothauer describes the production of polypeptides from whey using neutral proteases including Neutrase (see, e.g., claims 6-8 on page 20), acid proteases (see

Example 14 on pages 13 and 14), and alkaline proteases (see page 5, lines 15-16). Schlothauer describes the claimed variety of deactivation methods recited in claims 5-10 (see, e.g., pages 5-6), as well as the claimed immobilization techniques (page 5, lines 5-8). Schlothauer further discloses the preparation and use of the peptide MKG as recited in claims 15, 18, 21, 27 and 33 (see, e.g., page 4, lines 33-36).

Schlothauer differs from the claims under examination in that Schlothauer does not disclose the use of WPI as the starting material in the hydrolysis processes. However, Schlothauer generically discloses that the desired bioactive peptides can be made from a "whey protein containing substrate" (page 4, first line). Thus, the artisan of ordinary skill, recognizing from Davis that WPI is a whey protein containing substrate which can be hydrolyzed by the enzymes disclosed in Schlothauer, clearly would have been motivated to have used Davis's WPI in Schlothauer's process which uses a whey containing substrate. Thus, because WPI specifically fits the category of starting material required by Schlothauer, the artisan of ordinary skill would have been motivated to have used it in Schlothauer's process. Particular motivation would have been derived from the disclosure by Davis that protease-

hydrolyzed WPI yields peptide mixtures having anti-hypertensive activities. A holding of obviousness is therefore required.

Response to Arguments

All of applicant's argument has been fully considered to the extent applicable to the grounds of rejection set forth herein, but is not persuasive of error. It appears that the term "whey protein concentrate" as used in the prior art would be encompassed by the term "whey protein isolate" as recited in the claim, since a product containing protein concentrated from whey would also necessarily contain protein isolated from whey. However, note that prior art disclosing the hydrolysis of whey protein isolate (WPI) has been applied in this office action. Further, while it has not been established that these are terms of art having consistent art-accepted meanings, the terms "whey protein isolate: and "WPI" will be construed to mean the product defined in the Dairy Management, Inc. paper appended to the response of January 28, 2005.

In view of prior art disclosing the hydrolysis of whey protein isolate with the claimed enzymes, and in view of applicant's argument regarding the differences between WPI and WPC, the anticipation rejections set forth herein are clearly required. While applicant urges that none of the specific

peptides recited in the claims is disclosed in the prior art, the fact remains that the same starting material as recited in the claims was combined with the same enzyme as recited in the claims, and subjected to the same hydrolytic conditions. Therefore the same result must inherently have occurred, and that inherent result includes the presence the specific peptides recited in applicant's claims. For applicant to assert otherwise would be to urge that their own disclosure is non-enabling.

With respect to the issue of obviousness, and the demonstrations that protease-hydrolyzed WPI is less bitter than hydrolyzed WPC and more therapeutically potent, only the experiment described in the Table on page 17 clearly states with specificity what enzyme was used. However, at their broadest, the claims recite the use of any protease. Thus, to the extent that the reduced bitterness properties constitute a result not expected despite the prior art's suggestion of hydrolyzing WPI to make bioactive peptides, the claims are not commensurate in scope with this showing. See MPEP 716.02(d), discussing the fact that when a showing of unexpected result is made, only those claims commensurate in scope with that showing are properly considered to avoid the prior art. Moreover, the fact that applicant has recognized another advantage which would flow

naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP